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Ravensburg Regional Court

Minutes

recorded in the public session of the Ravensburg Regional Court, 4th Civil Chamber, on Thursday, 12.03.2015 in Ravensburg

Present:
Presiding Judge at the Regional Court Schneider
as presiding
Judge Dr. Brutscher
Judge at the Regional Court Percic
The appointment of a keeper of the minutes was dispensed with pursuant to sec. § Section 159 (1) of the Code of Civil Procedure.

In the legal dispute

Lawyers:
Lawyers **Gebhardt & Kollegen**, Eisenbahnstrasse 47/corner of Sieberstrasse, 66424 Homburg, reference number: 60453 RVB/kr

against
Dr. Stefan **Lanka**, Ludwig-Dürr-Weg 5/2, 88085 Langenargen, Germany
- Defendant -

Legal Representatives:
Rechtsanwälte **Wagner - Barth**, Bahnhofstraße 1, 66663 Merzig, Germany, reference number: 13-833-12

on account of awarding

appear when the case is called:

The plaintiff with RechtsanwanWältin Dr. Gebhardt,

the defendant with attorney Barth and Assessor Schreiner,
the expert witness Prof. Dr. Dr. Podbielski.

By reference, Dr. Gebhardt submits the motions from the **statement of claim dated writ** dated Nov. 20, 2013, sheet 2 and from the **supplemental writ** dated Aug. 1, 2014, Sheet 80.

Attorney Barth moves to **dismiss the complaint**.

The supplementary hearing of the expert is entered into.

He states
on the person:

Prof. Dr. Dr. Andreas **Podbielski**, Institute for Medical Microbiology, Virology and Hygiene, University Medical Center Rostock, Schillingallee 70, 18057 Rostock, Germany, 59 years old, university professor, not related to the parties by blood or marriage.

To the point:

First of all, I would like to present my written expert opinion of 17.11.2014 and my supplementary statement of 3 March 2015 as the subject of my remarks today.

In addition, I can respond to the questions of the Board:
In general, one should be careful with the terminology of "evidence" in biology, we actually only speak of "evidence".

When it comes to the connection between microorganisms and diseases, two questions must be kept apart.
to be distinguished. On the one hand, there is the question of whether there is a specific microorganism at all and what nature it has.
microorganism exists at all and what its nature is; on the other hand, it may have to be clarified whether it is actually causally significant.
causally significant for the disease; the presence of the microorganism alone can be used to
nism alone cannot prove such a causal relationship.

As far as the existence of the microorganism is concerned, there are many ways to collect evidence.
basically equivalent ways. Typically, in biology, we require that two independent paths are followed
independent ways to prove the existence of a microorganism and to classify it taxonomically.
and to classify it taxonomically.

The classical way is optical detection with microscopic methods. In the case of viruses
even work with the electron microscope. In this context, the question of size
the question of size always arises. However, the images and the question of size are normally of secondary importance.
secondary. The images are open to any interpretation and have little probative value in themselves.
evidential value, but only make things vivid.

On the other hand, the components of a pathogen can be detected. As such, only
proteins, carbohydrates and nucleic acids. Usually all three are present. Here one can
purification and detection methods.

In the case of a pathogen, one would typically expect that it can multiply.
can multiply. This is where the method of cultural detection of this germ comes from. This method is problematic
This method is problematic in that it does not always work because, for example, the multiplication of a germ in the laboratory is not always possible.
for example, the multiplication of a germ in the laboratory cannot be imitated without further ado. This applies to a large proportion of the germs
germs known today.

A further step can then be to regard the multiplication of the germ as a purification step and subsequently to
purification step and then subjecting the pathogen to another microscopic examination to determine whether the
microscopic examination of the pathogen to determine whether its appearance is unchanged.
It is also possible to check whether the biochemistry of the germ is still the same as before.

In addition to these methods, it is now possible to isolate and completely sequence the nucleic acids.
nucleic acids and to sequence them completely. From the outset, this represents an independent side path
which itself can also be decisive for the evidence.

There is a prominent example of this latter method with the hepatitis C virus,
which was never cultivated at all, but was analyzed immediately in its genome sequence. The nucleic acid sequence of the measles virus would also make it possible, for example, to produce a fully synthetic
microorganism fully synthetically in the test tube. On the one hand, this method is not entirely simple, and it is also subject to ethical questions. However, this shows the strength of the evidence of the nucleic acid sequence.

All these methods discussed so far, however, concern only the existence of the germ itself, nor

not its function as a pathogen.
As I understood the call for proposals, however, it was probably only a question of existence per se. itself.

At the request of the court. at least as a precautionary measure with regard to the causal relationship between micro-
organism and disease, to explain the meaning of Henle-Koch's postulates in more detail.
The expert explained:
These postulates are a mental support from a time when one had just learned,
that there can be a connection between microorganisms and infectious diseases.
tions. In their original formulation, the postulates were aimed at pathogens that were known at that time, i.e., from the time since
1850, i.e. at a time long before viruses were even known as such.
known as such. This latter circumstance at the same time illuminates the problem of applying certain rules to objects that are not known as viruses.
of certain rules to objects which are not known at all until after the formulation of the rule.
known at all.

The Henle-Kobh postulates in their classical form are four-part as already explained in my expert opinion.
my expert opinion. Because it has been found that, for certain pathogens that are recognized in pathogens, these postulates for the proof of causality cannot be fully complied with.
the postulates have been extended by typically three points. One of them is the only An-
The first is the aspect of the defense reaction, which emerged only at the beginning of the 20th century. One discovered things
such as antibodies or defense cells, with which the organism specifically fights the pathogens.
On the other hand, it was formulated that in in vitro experiments a cytopathology similar to that in humans
cytopathology should be similar to that in humans. This requirement is particularly important for viruses that are
do not live independently outside a human host organism.
Finally, the question is whether selective eradication can contribute to clinical recovery of the pa-
tients can contribute to clinical recovery.

With these three extensions, in varying combination with the original postula-
With these three extensions, in different combinations with the original postulates, these postulates can and must be applied to all pathogens known today.

Added to this nowadays is the genome sequence. Basically, one can read the genome sequence like a book.
genome sequence like reading a book. With a very high degree of probability, statements can be made about how an organism
about how an organism with a certain genome sequence behaves and what properties it shows.
properties it shows.

When asked by the court whether it is possible to prove the causality of infection with a pathogen in this last
in this latter form is possible exclusively on the basis of the genome sequence:
No, exclusively in this form it is not possible. Here, one can only obtain computer models
with correspondingly high probability values, but no direct proof can be obtained.
direct evidence.

After dictating up to here, the expert adds of his own accord:
I must make it clear that we cannot comprehensively determine the properties or behavior of an organism from the genome sequence alone.
properties or the behavior of an organism from the genome sequence alone. We can only determine structural features
and predict with a greater or lesser degree of probability how the organism will behave in a certain way.
in a certain way; a comprehensive statement about the overall behavior is still not possible.
genome sequence does not yet allow us to make a comprehensive statement about the overall behavior.

In response to a further question from the Chamber:
Of the total of certainly a good 10,000 scientific articles on measles, a large part deals
a large part is concerned with references to the disease, detection and control. With reference to the articles submitted by the plaintiff, it must first be stated that the contribution by Enders & Fee-
bles 1954 is certainly fundamental; it was the first article ever on this question. How
one wanted to evaluate the selection in all other respects is perhaps also a matter of taste. There may be
There may be some other articles, which at one or the other point would not have improved the evidence or the chain of evidence in the sense of the call.
chain of evidence in the sense of the invitation to tender could have been presented even more clearly.
Overall
I stand by my assessment that the six articles submitted meet the requirements of the call for
of the invitation to tender taken together.

The meeting was briefly interrupted.

After reconvening with the aforementioned parties, the Board discusses the understanding of the tender of the invitation to tender and points out that, in the opinion of the Chamber, the invitation to tender is to be very
that not only the mere existence of a certain micro-organism should be proved, but also that the organism, but also its causality for the measles disease.
disease.

In response to a question from the court as to whether the summarized assessment of the evidential value of the submitted

article not only with regard to the existence of the microorganism, but also with regard to its pathogenic property.

The expert explains that this may indeed be understood as far as it goes:
This may indeed be understood to that extent. In these articles it is practically
not only about the existence of the microorganism, but also about its pathogenicity.
property. I have also discussed this in detail in my expert opinion, in particular with regard to
the Henle-Koch postulates. I therefore also adhere to the following with regard to the pathogenicity of the microorganism.
of the microorganism, I maintain that the articles presented, when viewed together
and in particular with the inclusion of the review article of 1995 and the work mentioned there, the
and the work mentioned there, also provide evidence for the pathogenicity of the measles virus.

Upon further inquiry by the board, why the expert, despite methodological criticism of the individual original
the individual original papers, the expert also considered the proof of causality in the articles submitted by the plaintiff to be established.
articles submitted by the plaintiff:

I must say at the outset that, of course, any paper published in a scientific journal can have weaknesses.
journal can have weak points; the appropriate way for science to deal with such weak points
to deal with such weaknesses would be to present a scientific article of one's own and to
scientific article and discuss the issues.

Now, as far as the individual original articles are concerned, I can elaborate:

The article by Enders & Peebles 1954 definitely fulfills Henle-Koch's postulates
classical formulation No. 1 and 2. There is even a certain biochemical characteri-
(temperature sensitivity) and a statement about the size.
In the contribution of Bech & von Magnus 1958, the third classical Henle-Koch postulate is also fulfilled.
postulate is fulfilled. In this contribution, we have additionally proved the defensive reaction, which in the
extended version of these postulates as stated is of concern. In fact, however, an
experiment in the sense of the 4th classically formulated Henle-Koch postulate was not carried out at that time.
carried out at that time.
As far as the other three original papers are concerned, these are mainly concerned with size
and electron-microscopic representation of the measles virus and fall out of this evaluation
to a certain extent.
The review article of 1995 cites and then presents several more articles which, with regard to the measles virus, have all been published.
all postulates No. 1 to 4 in the classical formulation with regard to the measles virus. Therefore
Therefore, it can be stated that the presented articles do indeed fulfill Henle-Koch's postulates in the classical formulation.
late in the classical formulation. In addition, as already mentioned, the defense reaction

cytopathology, namely the formation of syncytia, i.e. cell fusions, as typical for paramyxoviruses.
fusions, as typical for paramyxoviruses, to which the measles virus belongs.

At the request of the court:
I cannot say now whether there is an article that comprehensively presents the same things
as the mentioned original articles without showing their methodological weaknesses, for example with the
For example, with the negative controls that are indeed missing. In this context, I would like to
again that certain parts of the experimental design in the original articles of '54 and '54 are missing.
articles of '54 and '58 do have a certain control function.
The following seems to be crucial to me: Such scientific articles are used
for follow-up work also by other scientists. A good purification mechanism has been established in the literature.
established a good purification mechanism in the scientific literature, which, especially in recent times,
has in part included articles from the highest-ranking scientific journals.
recently affected articles from top-ranking journals. If the processes described in the article
cannot be reproduced at all in subsequent experiments, this is typically found in articles by other researchers.
of other researchers. In any case, in the case of a topic such as measles, which is
as measles, this would certainly have been expected.

The expert adds on his own initiative:
It is quite conceded that once certain things are widely accepted in the scientific world, it is not
accepted in the scientific world, it is not easy to publish contrary results.
you have to fight against it. On the other hand, however, it is an extremely high
broadly accepted thing, it is an extremely high incentive for scientists, if only in terms of reputation, to
reputation alone, to publish new and better findings. Experience shows
experience also shows that such refutations can then be published at a very high level.
ned. Against this background, too, one would really have to reckon with the fact, despite all difficulties, that for well
that a publication would be found for well-documented results to the contrary.

In response to a question from Assessor Schreiner, he asked whether the distinction made by the expert between
between proof and evidence meant that a proof for the circumstances in question here was
was ultimately not to be led:
I have to clarify as to the terminology that proof in the classical sense, such as in
mathematics or physics in biology. In biology
biology, only circumstantial evidence can be collected from the outset.
in their aggregation practically have probative value.

On follow-up by Assessor Schreiner. whether this circumstance would diminish the probative value:
No, the way biological research has been done for many decades, it does not.

In response to a question from Assessor Schreiner, whether the criticism of the early original work. such as that the 1954 work does not fulfill Henle-Koch's postulate 3. does not lead to the fact that this work.
that this 1954 work does not fulfill Henle-Koch's Postulate 3.
that these works are useless, or whether one can base anything at all on such works:
It is not the task of technical articles on microbiological matters that every technical article for all four of these Henle-Koch postulates; as we can see, some articles do not even deal with this issue. As we can see, some articles do not deal with them at all. Each article has its own scope and its work content. If one wanted to satisfy in one article the demands of all four of Henle-Koch's postulates in one article, the article would probably be so voluminous that, given the editors' guidelines
that it might not even be publishable in view of the editor's requirements. For
In itself, therefore, this is not a shortcoming.

When asked by Assessor Schreiner whether, beyond the publisher's specifications, there might be books or dissertations of a corresponding kind existed:
Dissertations are difficult to see. An original monograph, which for the first time presents own investigations of the kind in question would not be known to me.

In response to a question from Assessor Schreiner, whether the previously recorded statement of the expert
about publications mentioned in the review article from 1995 did not mean that there were indeed publications which
publications which fulfill all four Henle-Koch postulates:
I must clarify that my previous statement was not meant in this sense.
I can only say that individual aspects of the later works presented in the review article can also be considered as fulfilling certain postulates.
can be regarded as fulfilling certain Henle-Koch postulates. A single
single work, which would fulfill all four postulates, is really not known to me.
known.

In response to a question from Assessor Schreiner as to whether, for the classification of a publication as a "scientific publication
scientific publication", it is not necessary, in addition to the control system mentioned by the expert that there are further controls as to whether the experiment was carried out properly and, in particular, documented.
experiment has been carried out properly and, in particular, has been documented:
The obligations to document what is behind a scientific article have changed in the

The market environment has changed, in some cases dramatically, over the past 50 years. An important aspect in this respect is
the possibilities available today, in particular through electronic media, which allow data to be provided which allow data to be made available to a much greater extent. The documentation requirements for scientific
scientific journals were certainly much narrower in the 1950s than they are today.

In response to a question from Assessor Schreiner. whether it would not be terribly easy. to make up for the attempts made at that time
with today's means and to publish an article today that is not subject to any methodical criticism.
to publish an article today that is not subject to any methodological criticism:
I have already explained in my expert opinion and supplementary statement that, on the one hand, there is an economic
that, on the one hand, there is an economic efficiency requirement for the research institutions; one will not receive funds from any
no financier will provide funds to prove things that are already considered proven by experts.
as proven in the scientific community. One will also not find a publication organ for such work.

On the interjection of Assessor Schreiner. that the provenness is just a problem:
At any rate, the overwhelming mass of scientists understands these very things as presented
as proven.

On the question of Assessor Schreiner, which are the components of the measles virus, in particular whether the
in particular whether the measles virus contains ribosomes:
No, the measles virus does not contain ribosomes. The common definition of the virus is that it has no ribosomes,
that it does not have ribosomes.

Assessor Schreiner then addresses the defendant's alleged communication from the Robert-Koch-Institut, according to which ribosomes are contained in the measles virus.
such a statement would not, as it were, throw the whole concept of the measles virus overboard:
Such a statement would indeed be astonishing, it would attract the greatest attention of the scientific community and could be
and could be published with the prospect of great effect.
could be published with great effect. The concept of the virus would, of course, not necessarily be overthrown by this.
The conceptual understanding of the virus is certainly in flux.

The expert adds on his own initiative:
I would like to clarify that this last statement concerns the concept of the virus as a whole.
For example, viruses have been described that are much larger than bacteria. Here, difficult
difficult taxonomic questions. With regard to the measles virus, however, such questions arise.

not at the present time.
In response to a question from Assessor Schreiner. as to whether the expert would also consider a summary of already
publications that have already appeared without reproducing his own research results as scientific work.
scientific work without reproducing his own research results:
Yes, of course.

In response to a question from Assessor Schreiner as to whether this also applied in particular to the review paper from 1995 submitted by the plaintiff: "Yes, of course.
review paper from 1995 submitted by the plaintiff:
Yes. This work has been published in a journal that is peer-reviewed.
stern). Such reviews are also reviewed in advance,
for consistency of presentation and conclusions drawn, and also for inclusion or exclusion.
inclusion or exclusion of relevant articles. The omission of own research results
research results is a mandatory prerequisite for this type of publication.
is meticulously ensured that no mixing takes place here.

Upon follow up by Assessor Schreiner. whereupon the review takes place:
Whether in fact those parts of the original articles that are reproduced in such a review are reproduced correctly and whether they are not mixed.
are reproduced correctly and whether the relevant parts are selected;
On the other hand, in such a review, from the various original articles (each of which is a conclusion in itself)
conclusions are drawn from the various original articles (each of which drew its own conclusions from its research results).
conclusions are drawn. The review article is examined to determine whether these new conclusions are coherent and sound.
seem coherent and consistent.

In response to a question from Assessor Schreiner as to whether the expert could now readily state which of the
which original articles cited in the 1995 review fulfilled the Henle-Kochian postula- tions 1 to 4?
1 to 4 were fulfilled:
No, I cannot do that off the cuff now. I must remind you, however, that not all four postula
all four postulates must be fulfilled for a pathogen to be accepted as such.
As already mentioned, there are recognized pathogens for which not all four postulates can be fulfilled.
can be fulfilled. In this respect, these postulates have been softened as described.

The meeting was interrupted for consultation and then continued with the above-mentioned parties. continued.

When asked by Assessor Schreiner how big the measles virus is now:
I can't give any numerical order of magnitude from memory. I have already explained in detail in my in detail in my expert opinion that and why it is a matter of variable size orders, which are
The figures are to be found in the literature discussed in this regard.

In response to a question from Assessor Schreiner. whether all six articles submitted were listed:
Yes, to my knowledge the mentioned database NCBI only lists articles that come from journals with peer-review system.
with peer-review system.

In response to a question from Assessor Schreiner as to how, with reference to the article by Daikoku et al.
2007, the typical changes of the cell mentioned on the one hand are related to the different different sizes or shapes shown on the other hand:
I would actually have to read the article again carefully for that. I cannot say anything about this here and now not immediately something say.

No further questions are addressed to the expert.

The expert approves his statements after loud dictation and under all-round express waiver of renewed questions.
express waiver of rehearing.

The parties shall argue on the result of the evidence and on the merits of the case with the motions set out at the beginning.
motions set forth at the outset.

No further motions are filed.

The session is interrupted once again.

Upon recall, by reading aloud the judgment formula, the following judgment is pronounced:

1. the defendant is ordered to pay to the plaintiff:

a) EUR 100,000.00 plus annual interest thereon at the rate of 5 percentage points above the respective prime rate since 1.5.2012,

b) EUR 2,924.07 for extrajudicial costs,

c) 492.54 EUR plus annual interest thereon in the amount of 5 percentage points above the respective base rate since
the respective prime rate since April 16, 2014.

2. the costs of the legal dispute shall be borne by the defendant.

(3) The judgment shall be provisionally enforceable against security in the amount of 110 % of the amount to be enforced.
amount to be enforced in each case.

The expert is discharged without being sworn at 12:30 p.m.

Schneider
Presiding Judge of the Regional Court

Rief, JHSekrin
as Clerk of the Court Office
at the same time for the correctness and completeness
the correctness and completeness of the transmission from the audio carrier.